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Master of Philosophy Degree in International Community Health

Assessment of Type 2 Diabetes management practice: A study in public hospitals outpatient clinics, Khartoum and Gezira, Sudan

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"Cancer, diabetes, and heart diseases are no longer the diseases of the wealthy. Today, they hamper the people and the economies of the poorest populations even more than infectious diseases. This represents a public health emergency in slow motion."

Ban Ki-Moon, United Nations Secretary-General

"I have high blood sugars, and Type 2 diabetes is not going to kill me. But I just have to eat right, and exercise, and lose weight, and watch what I eat, and I will be fine for the rest of my life."

Tom Hanks, famous American actor and diabetes patient

"The doctor of the future will give no medicine, but will the patient in the proper use of food, fresh air and exercise."

Thomas Edison, American inventor and businessman

ABSTRACT (300 words)

ASSESSMENT OF TYPE 2 DIABETES OUTPATIENT MANAGEMENT PRACTICE IN PUBLIC HOSPITALS, KHARTOUM AND GEZIRA STATES, SUDAN

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BACKGROUND: Type 2 diabetes is a major public health problem with an estimated prevalence of 8.3% among adults in 2013. Majority of diabetes mortality occurred in low and middle income countries as almost 80% of people with diabetes lives in these countries. Diabetes care exerts a tremendous economic burden on patients, families, health systems and the society as a whole.

AIM: The main objective of the study is to investigate the care providers' adherence to the national guideline on type 2 diabetes outpatient management. Furthermore, to compare documented diabetes care services between the public hospitals and the specialized diabetes center.

METHODS: This hospital based cross sectional study was in three public hospitals in Khartoum and Gezira states. Medical records reviewing and quantitative questionnaire included 261 patients (mean age, 54 ±14.5 years; diabetes duration, 8.1 ±7.6 years). Additionally, Medical records of 157 patients were reviewed in a specialized diabetes center (mean age, 56 ±11.4 years; diabetes duration, 10.0 ±7.0 years).

RESULTS: Frequency of documentation of diabetes process measures in public hospitals was: Blood glucose tests (67.2%), HbA1c (22.9%); foot exam (14.1%); Fundoscopy (9.2%); lipids

profile (17.2%); urinalysis (15.6%); and RFT (29.4%). Patients reported excess of received diabetes care measures compared to what is documented. In the specialized diabetes center, the frequency of documentation of the previous measures was significantly higher.

CONCLUSIONS: The study identifies various areas of suboptimal diabetes care for potential improvement. Based on revised clinical notes, screening for diabetes complications is a low adherence area as the screening tests were documented in less than one third of the tested sample. We also found discrepancy between the documented diabetes care measures and the performed measures as reported by patients. The previous finding could indicate lack of proper documentation of the medical consultations.

Keywords: adherence, type 2 diabetes, guidelines, outpatient management.

List of Abbreviations

ADA	American Diabetes Association
BMI	Body Mass Index
BP	Blood Pressure
FBG	Fasting Blood Glucose
FMoH	Federal Ministry of Health
HbA1c	Glycosylated Hemoglobin
HDL	High Density Lipoprotein
GDP	Gross Domestic Product
IDF	International Diabetes Federation
IDPs	Internally Displaced Persons
LDL	Low Density Lipoprotein
LMICs	Low and Middle Income Countries
RFT	Renal Function Test
WHO	World Health Organization

1. Introduction

1.1 Sudan background:

1.1.1 Country profile:

Sudan is the third largest African country with an area of 1.9 million square kilometers. According to the 2012 census, its population is estimated around 36 million, with 17% of the population living in the capital city, Khartoum (1). Sudan has 853 kilometers long coastline with the Red Sea and share borders with seven countries namely Egypt, Libya, Chad, Southern Sudan, Central African Republic, Eritrea and Ethiopia. Sudan has a characteristic location linking between the Arabic North African countries and Sub-Saharan Africa. Its terrain is generally flat, featureless plain, mountainous in the northeast and west while the north is dominated by desert (9).

Sudan's geography and the vast distances between populous areas combined with the poor roods and transportation infrastructure affect the delivery of health care services. The free borders with multiple countries help transmission of communicable disease and reduce the efficacy of diseases control programs.

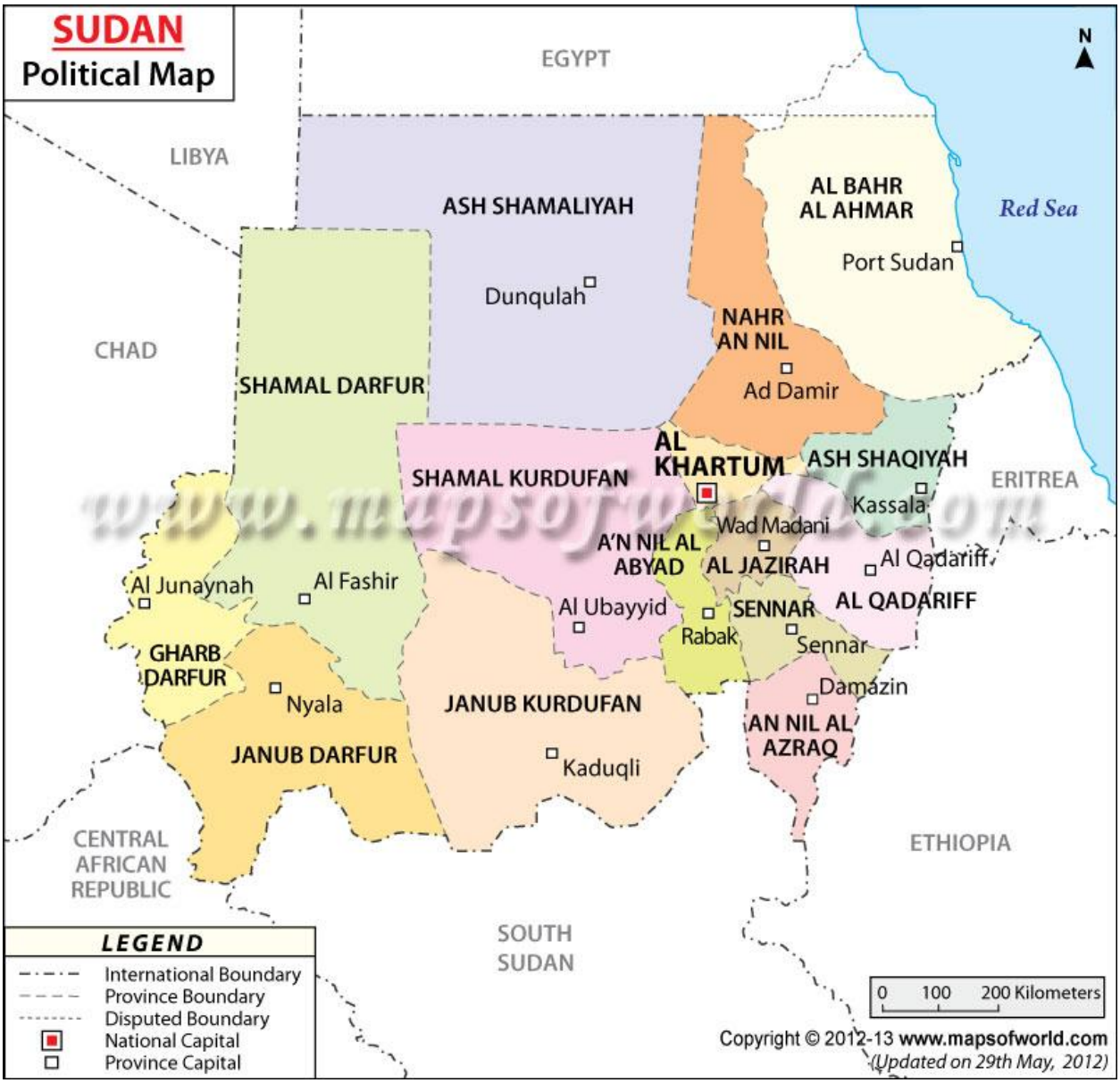
1.1.2 Demography:

According to the national census performed in 2012 after the secession of South Sudan, total population was estimated at around 36 million, growing by a rate of 2.8% annually, 49% of the population living in urban areas with 17% of the population living in the capital city, Khartoum (12). The country has a wide range of ethnicities and cultures which constitute a combination of indigenous inhabitants of the Nile Valley, and descendants of migrants from the Arabian Peninsula (2).

Almost 8% of the population is nomads in cyclical migration, seeking natural resources and grazing areas. There are more than 2 million Internally Displaced Persons (IDPs) in Sudan due to the long standing conflicts and disputes. 1.4 million IDPs reside in institutions while the rest live in refugee camps (13).

The average household size is 5-6 individuals, fertility rate is 5.6 children per woman; crude birth rate is 31.2 and crude death rate is 16.7 per 1,000 people. Life expectancy at birth is 59 years which is slightly higher for females (14).

Figure 1.1.1 Sudan boundaries, states and important cities



1.1.3 Economy:

Sudan is considered rich in natural resources and agricultural capacity but failure to manage these resources combined with protracted conflicts and political instability created an extremely poor country. Recent economic indicators showed that the Gross Domestic Product (GDP) equals to $159.5 billion growing at a rate of 3% in 2014 and Per capita GDP of 4,500 USD. According to the Human Development Index (HDI), developed by the UN Development Program (UNDP) in 2013, Sudan is ranked number 166 out of 187 countries (15). Since the year 1999, the national budget was dependent on oil exports but with the separation of South Sudan in 2011, three quarters of the oil production were lost. However, there is slight economic growth currently, due to non-oil exports such as Arabic gum and gold mining. Nearly half of the population is considered below poverty line with less than one US dollar earning a day (16). The unemployment rate estimated in 2012 was 20% while 80% of the working force employed in agriculture (16).

1.1.4 Health care system:

The Ministry of Health (MoH) is the main health care provider and it is organized in a three-tier system. The Federal MoH is responsible for formulation of national health strategies, training, monitoring, evaluation and relations with external organizations. The State MoH has the same responsibilities confined only to the state level, in addition to funding and implementation of health plans. Localities are involved directly in health care delivery to the community through primary health care approach which includes Primary Health Care Units (PHCU), physician health centers, dispensaries and dressing units (22). The second level includes rural hospitals which have more trained staff and capacity to receive emergency cases. The capacity of these hospitals is usually 30-50 beds and represents the first referral care. The tertiary level includes the specialized hospitals found in the state capitals to represent the second referral destination (23).

Sudan's economy has suffered a major shock from the loss of oil exports revenue after the separation of South Sudan which represented 75% of the country's budget. Consequently, health and other social sectors became underfunded which resulted in several health programs being

funded by international organizations either directly or through the Ministry of Health. Thus, these donor funded programs are organized in a vertical fashion and not fully integrated into the main stream health care system. Health insurance program, besides its role in funding individual patients, is a main health care provider through its owned health facilities. Other governmental sectors such as armed forces, police and certain universities run a considerable percentage of public hospitals (23).

1.1.5 Diet and life style:

Rural areas in Sudan are more affected with the economical adversity and the ongoing civil conflicts, which led to populous migration towards urban areas. Consequently, the population adopted more sedentary life style and developed unhealthy eating habits such as heavy consumption of sugar and refined wheat. Vegetables and fruits are not widely used because of the high cost of storage and lack of health education.

In 2011, a national qualitative study was conducted to assess the health risk behavior associated with non-communicable diseases. The study found that few respondents were engaged in regular exercise. Although the awareness about healthy diet was adequate, majority of respondents had contradictory attitude. Most of the respondents had higher consumption rates of red meat, white sugar and salt while fruits and vegetables were less frequently used (18).

1.2Diabetes mellitus

1.2.1 Diabetes definition and classification

Diabetes mellitus is a chronic, lifelong disease caused by deficiency or resistance of the hormone insulin which regulates the level of glucose in the blood. The marked hyperglycemia associated with diabetes gives rise to serious microvascular and macrovascular complications and damage of many body's systems. Table 1.2.3 summarizes the diagnostic criteria for diagnosing diabetes and intermediate hyperglycemia as recommended by the World Health Organization (WHO) (3). There are three major types of diabetes namely type 1, type 2 and gestational diabetes. The chronic types of diabetes (type 1 and type 2) have different etiological factors (table 2).

1.2.2 Complications of diabetes

Diabetes is a systemic disease that affects most of the body organs especially heart, blood vessels, kidneys, eyes, nerves and teeth. In high income countries, diabetes is the leading cause of chronic heart diseases, renal failure, blindness and non-traumatic lower limb amputation (4).

Numerous complications may arise as a result of diabetes, which include the following:

Cardiovascular diseases:

Chronic hyperglycemia and dyslipidemia affecting the blood vessels is a major cause of atherosclerosis which may lead to fatal myocardial infarction or cerebral stroke. Cardiovascular diseases are the most common cause of mortality in diabetic patients. (4)

Diabetic nephropathy:

The metabolic and hemodynamic changes associated with diabetes can lead to glomerular sclerosis and fibrosis. Diabetic nephropathies manifest as progressive albuminuria, increased blood pressure and even end-stage renal disease. Type 2 diabetes leads to renal failure in 20-30% of patients especially in patients with longer duration since diagnosis (usually ≥10 years) (5).

Diabetic eye disease:

A range of eye problems may occur as a complication of diabetes, which include:

Diabetic retinopathy: damage to the small vessels in the retina leads to poor vision or even blindness.

Cataract: Diabetes accelerates the onset of cataract which is clouding of the eye lenses.

Glaucoma: increase in the vitreous fluid pressure resulting in optic nerve damage, retinal detachment and loss of vision.

It is estimated that 39 million cases of blindness worldwide are caused by diabetes and 248 million diabetics are visually impaired (24).

Diabetic neuropathy:

Diabetes affects the small vessels that supply the nerves which lead to neuronal dysfunction especially in the peripheral nerves and the autonomic nervous system. Adverse consequences of diabetic neuropathy include diabetic foot ulceration and lower limb amputation, diabetic gastropathy and erectile dysfunction in men. In addition, it may mask the symptoms of ischemic heart disease, resulting in the clinically ambiguous silent angina.

Table 1.2.3 WHO diagnostic criteria of diabetes and intermediate hyperglycemia

Diabetes mellitus	
Fasting plasma glucose	≥7.0mmol/l (126mg/dl)
or	
2–h plasma glucose*	≥11.1mmol/l (200mg/dl)
Impaired Glucose Tolerance (IGT)	
Fasting plasma glucose	< 7.0mmol/l (126mg/dl)
and	
2–h plasma glucose*	≥7.8 and <11.1mmol/l (140mg/dl to 200mg/dl)
Impaired Fasting Glucose (IFG)	
Fasting plasma glucose	6.1 to 6.9mmol/l (110mg/dl to 125mg/dl)
and (if measured)	
2–h plasma glucose*	<7.8mmol/l (140mg/dl)

Classification of diabetes according to etiological factors	
Type 1 diabetes (complete lack of insulin due to destruction of beta cells in the pancreas)	**Type 2 diabetes** (insulin resistance with or without reduced insulin secretion)
Autoimmune Idiopathic	Multifactorial (genetic susceptibility combined with other behavioral risk factors) Hereditary beta cell dysfunction Genetic defects in insulin processing or action Exocrine pancreatic defects Endocrinopathies e.g. Acromegaly Viral infections Drugs

1.2.3 Diabetes care

Diabetes is complex and multisystem disease that requires management through systematic and multifaceted approach which relies on certain clinical guidelines. Periodical guidelines on management diabetes are provided by major organizing bodies such as the World Health organization (WHO), International Diabetes Federation (IDF) and the American Diabetes Association (ADA) (25-27). The previous guidelines stated that management of diabetes should not be confined to lowering the blood glucose level only but also extend to life style modifications and lowering the risk of developing diabetes complications. Moreover, it emphasizes on educating patients on self monitoring and management. Additionally, the IDF published guidelines in 2013 regarding management of type 2 diabetes in older population (28). The guidelines provided solutions for numerous challenges in management of diabetes in old people with special focus on long term diabetes complications. The guidelines, also, addressed less commonly tackled areas such as pain management and end of life care.

In 2011, the Federal Ministry of Health in Sudan constituted national guidelines to manage different types of diabetes (48). The guidelines were mainly based on the WHO recommendations but certain modifications were introduced to adapt to the local setting,

especially the financial aspect. In our study, these guidelines were considered the standard reference for diabetes care in Sudan. The following points highlight the main features of the above mentioned guidelines:

- The recommended management team consists of, at least, a general practitioner, diabetes educator, Nutritionist and a nurse. High risk patients should be referred to specialized units for screening and management of diabetes complications.
- In addition to the management team, the outpatient clinic should include adequate space and time for patients, system of documentation of diabetes consultations and means of referral and communication with specialized units.
- The guidelines define four areas to be included in the comprehensive management of diabetes patients:
    1. Medical history: Characteristics of patients, life style and eating patterns, drug history, diabetes-related complications and knowledge about self-management.
    2. Complete physical exam: BMI, blood pressure, comprehensive foot exam, Fundoscopy, neurological exams.
    3. Laboratory assessment: blood glucose tests (FBG, RBG and HbA1c), fasting lipid profile and urinalysis for microalbuminuria.
    4. Treatment plan: Medications used in glycemic control and treatment of associated risk factors i.e. dyslipidemia, hypertension and obesity.
- The detailed plan of the tasks that should be performed during the follow-up visit and annual review are shown in Table 5. The guidelines lacked recommendations on the structure of medical documentation e.g. predesigned medical card/file for diabetes consultation. Thus, in developing the review checklist for the current study, we assumed that all the suggested tasks should be documented.
- The guidelines mentioned two tests for monitoring of glycemic control, which are fasting and postprandial glucose level (at each visit) or HbA1c (every 3 months). In contrast to the international guidelines published by the WHO and the IDF where HbA1c is the only recommended test for monitoring of glycemic control. The added option may be due to the high cost and reduced availability of HbA1c in Sudan.

Table 1.2.3 Components of the medical consultation during diabetes follow-up visits

Review topics	Initial review/ Referral	Regular	Annual review
Long term and/or recent diabetes history	✓	✓	
Life style review	✓	✓	
Complications history and/or examination	✓		✓
Smoking history	✓	If problem	✓
Drug history / current drugs	✓	✓	✓
Weight/ body mass index	✓	✓	✓
General examination	✓		
Foot examination	✓	If problem	✓
Eye vision examination	✓	If problem	✓
Blood pressure	✓	If problem	✓
Glycosylated hemoglobin	✓	✓	✓
Lipid profile	✓	If problem	✓
Urine protein	✓	✓	✓
Serum creatinine	✓	If problem	✓

- The guidelines emphasize that foot care is essential in diabetics and all physicians must perform foot exam regularly. Also, physicians should advice patients on suitable shoes, nail cutting and self inspection of the feet.
- In type 2 diabetes, unlike other types of diabetes, screening for diabetes complications should start directly after the establishment of the diagnosis and continue annually.
- The guidelines provided standard targets for diabetes care measures and laboratory tests. The standard targets differ occasionally from the targets recommended in other guidelines, so it is assumed that it is more compatible with diabetes patients in Sudan or the region. The following table shows the recommended targets for diabetes care.

Targets of diabetes care measures/tests

Test/ measure	Target value
Blood pressure, mmHg	<130/80
Body mass index, Kg/m2	<25
HbA1c, %	<6.5
Total cholesterol, mg/dl	<200
LDL cholesterol, mg/dl	<100
Serum creatinine	<1.09

1.2.4 Global burden of Diabetes

In 2013, the international Diabetes Federation (IDF) estimated that 382 million people suffer from diabetes worldwide, with a prevalence of 8.3% among adults (16). There is a great increase in the prevalence of diabetes especially in developing countries due to the epidemiological transition of health risks towards modern risks such as sedentary life style and unhealthy food rather than the health risks associated with communicable diseases. The increase in the prevalence of diabetes could also be caused by improved survival and aging of people and improved disease detection and diagnosis.

Chronic non communicable diseases, including diabetes, are the leading cause of death globally. WHO recent estimates showed that diabetes caused 1.5 million deaths in 2012, constituting 2.7% of total deaths (18). Majority of diabetes mortality occurred in low and middle income countries as almost 80% of people with diabetes live in these countries.

The burden of diabetes is clearly underestimated as statistics showed that almost 50% of diabetes cases are undiagnosed worldwide (the IDF estimated 175 million undiagnosed cases currently) (16). Late diagnosis is a major issue as it reduces the chance of preventing long term complications of diabetes. Moreover, the mortality is less quantified as diabetes is not recorded as the cause of death in considerable proportion of cases but the cause is attributed to its complications that led directly to death (17). For example ischemic heart disease is the leading cause of death worldwide (7.4 million deaths in 2012) and it is a prevalent complication of diabetes.

Diabetes is the leading cause of the following: Chronic Kidney Disease (CKD), adult onset blindness and non-traumatic lower limb amputation (19-21). Also, it is a major cause of stroke and ischemic heart disease.

1.2.5 Diabetes in Sudan

Knowledge of the diabetes epidemic in Sudan is deficient as there is no national survey or large scale studies to quantify the burden of the disease on the country. The WHO and the IDF published estimates on the prevalence and burden of diabetes in Sudan depending on small scale reports, comparisons to similar countries and predictive models, thus, high degree of uncertainty is suspected.

The WHO estimated the prevalence of type 2 diabetes in Sudan to be 3.5% among males and 3.4% among females (16). The previous WHO figures are suspected to be adopted from a small-scale study conducted in 1996 to estimate the prevalence of type 2 diabetes in northern states with a sample of 1,284 subjects aged 25 years or more (17). In 2014, the IDF estimated that 16% of Sudanese adults (20-79 years) suffer from diabetes, with a total of 3 million diagnosed patients and additional 1.5 million cases suspected to be undiagnosed (18).

Another study carried out in 1998 indicated a higher prevalence among Danagla community; a major tribe resides in northern Sudan. The prevalence of type 2 diabetes was 8.3% (men 9.9%; women 7.5%) and showed no differences between rural and urban areas (19).

In recent years, the Federal Ministry of Health (FMoH) conducted small scale studies, in line with the 2010 Sudan Household Survey (SHHS) (14), to calculate the prevalence in different areas of Sudan. The figures showed great differences between various regions. The prevalence of type 2 diabetes ranged from 2% in the western most state of West Darfur to as high as 24% in the Northern state. The FMoH estimated that the prevalence of type 2 diabetes in Sudan should be around 14.5%. In 2006, the Ministry of Health in Khartoum state estimated the prevalence in Khartoum to be 19.2%. The previous figures are not published as they were not calculated through a specific national survey to measure the prevalence of diabetes. These estimates were directly collected from the department of non-communicable diseases in both ministries.

In addition, Diabetes care exerts a tremendous economic burden on patients, families, health systems and the society as a whole. Direct costs of diabetes include expenses of diagnostic tests, diabetes medications, outpatient consultations, hospitalizations and travel to health facilities. Additionally, there is greater burden of indirect costs such as disabilities, short illnesses, time of family caregivers and psychological issues. There is paucity of information on the expenses of diabetes control in Sudan. M.Eltom et al. and associates estimated the direct costs of managing type 2 diabetes in Khartoum as 175 USD per year. The previous study found no relation between higher cost of diabetes care and optimum glycemic control, as 77% of patients (total of 822) had unsatisfactory level of HbA1c (17).

1.3 Literature review of relevant studies:

1.3.1 Search strategy

The literature search involved review of mainly two online data bases, PubMed and Google scholar. The used search key words, the number of hits and the narrowing criteria are listed below:

#1 management of type 2 diabetes : 3546 Hits
#1 #2 assessment OR evaluation OR audit : 650 Hits
#1 #2 #3 publication date: last 10 years
#1#2#3 #4 Review articles: 185 articles

There were two articles suggested by an expert. So, the total number of retrieved articles for further review at the title/abstract level was 187 articles. The following diagram shows the pathway to obtain the relevant articles which were included in the literature review.

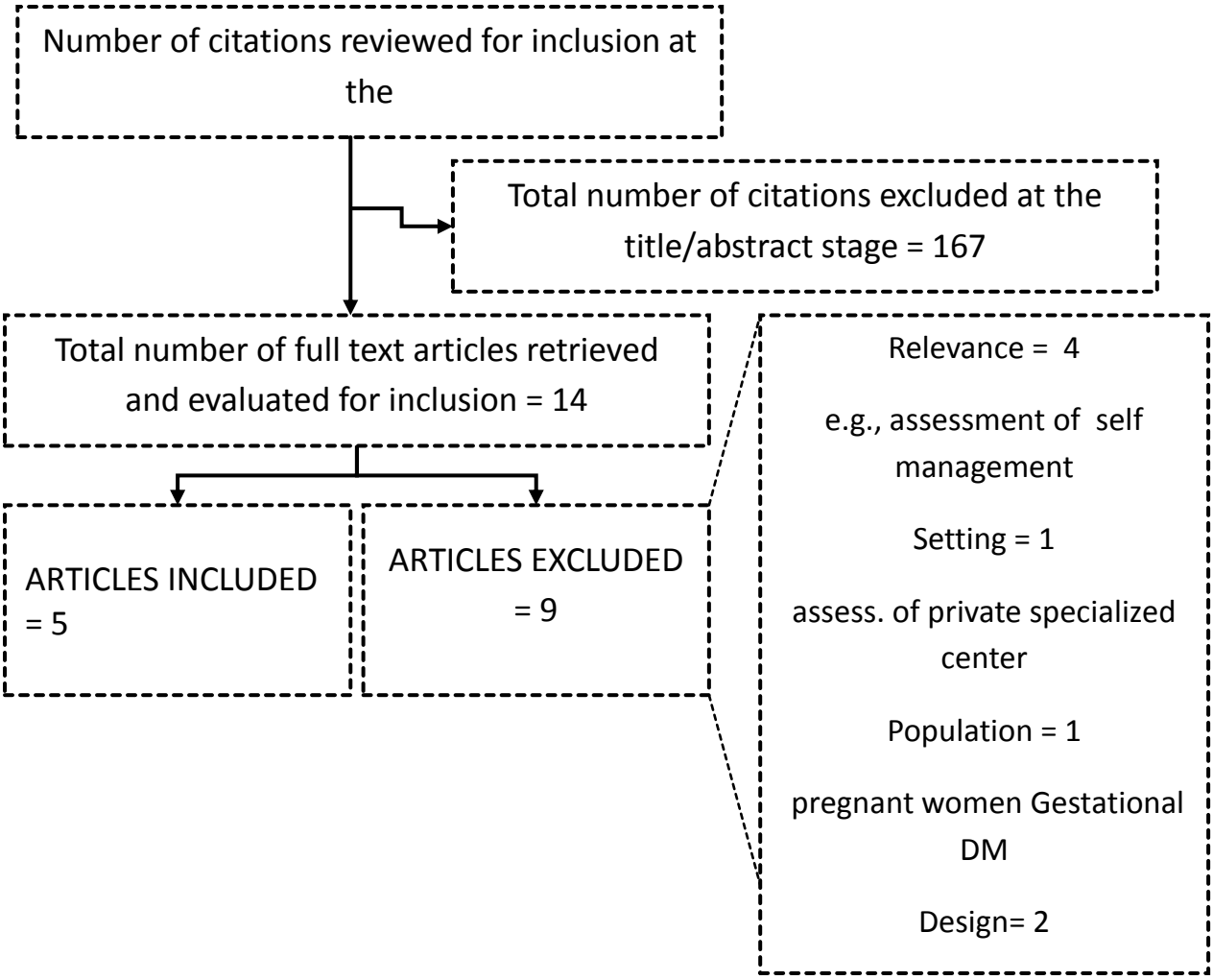


Figure 1.3.1: search strategy for relevant articles

1.3.2 Overview of the relevant studies

Generally, the used methods in the relevant studies are different according to the study setting. In developed countries, clinical auditing is an establish practice in health facilities. Thus, the published studies tried to assess the outcome of management or to target particular health care level e.g. family doctors. In developing countries, the studies usually aim to describe the management practice and implementation of clinical guidelines. Another difference, the quality of medical documentation in low income settings is often questionable, so additional tools such as interviewing diabetes patients and health care providers are applied. In developed setting, review of medical records is the main tool for assessing diabetes management.

In low resource settings, it is widely noticed that the patients tend to bypass the primary care level in favor of higher level of care despite the greater time and financial costs. Although there is no study in Sudan to prove the previous fact, it is well documented in similar developing countries. Consequently, the studies conducted in developing countries tend to target hospitals as diabetes patients usually seek care in the secondary level, in contrast to the developed countries, where the follow up of diabetes patients is provided mainly through family physicians or general practitioners.

1.3.3 Knowledge gap

There is limited research on diabetes and other communicable diseases conducted in Sudan. The rapid epidemiological shift towards communicable diseases is unmatched with change in research priority and funding. In regard to the management of type 2 diabetes in Sudan, there is lack of tools to measure the implementation of published guidelines. For example, clinical auditing of diabetes is not widely implemented to assess the quality of provided care. In addition, scarcity of published studies on quality of diabetes management in Sudan creates a wide knowledge gap in the field. The reviewed studies lacked comparison of the documented diabetes measures to the measures reported by patients. The previous finding gives better understanding of the quality of diabetes care, as collecting data solely from medical records could underestimate the performance.

1.3.4 Rationale of the study

The prevalence of non-communicable diseases, including diabetes, is increasing globally without equivalent increase in research and funding to combat these diseases. In Sudan, and other developing countries, the increase is more dramatic due to the changes in life style and aging of the population. So, the developing countries are struggling with double burden of risk factors for communicable and non-communicable diseases. In a setting of low human and funding resources, the current practice of managing diseases needs to be consolidated to obtain the desirable outcome.

Assessment of the management practice is essential to evaluate the impact of current and future interventions. It is also important to understand the extent of implementation of published guidelines. Thus, such studies can trigger health facilities to establish a routine clinical audit to monitor the performance of care providers and transmit feedbacks to the policy makers.

Additionally, assessment of the practice helps further studies to assess the outcome of the used management guidelines. Based on the reviewed literature, most of the studies were assessing the outcome measures of diabetes care and attainment of the standard management goals. But, in most developing countries the management practice and the medical documentation is lacking which affect assessing the management outcome. As to best of my knowledge, there are no published studies on describing the follow up and management of type 2 diabetes in the outpatient settings in Sudan, so I would like to explore this gap.

2. Objectives of the study

2.1 General objective

The main objective was to map the adherence to clinical guidelines for management of type 2 diabetes in outpatient clinics using review of medical records and reporting of patients on provided diabetes care services.

Research Question:

What is the level of adherence between the guidelines for management of type 2 diabetes and the actual practice in outpatient clinics in Sudan?

2.2 Specific objectives

- To evaluate the degree to which type 2 diabetes patients receive the recommended diabetes care measures regarding glycemic control, life style interventions and risk assessment as outlined in the national guidelines on management of diabetes.
- To compare documented diabetes care services between the public hospitals and the specialized diabetes center.
- To identify which of the patients' characteristics and disease related variables have a significant relation with the receipt of diabetes care.
- To know the frequency of diabetes complications. The study focuses on the common complications of Type 2 diabetes that affects the eyes, feet, heart and kidneys.

3. Methods

3.1 Study design and setting

The study conducted as a descriptive cross sectional, hospital based study. The study was based on collecting primary data (patients' questionnaires) and secondary data (review of medical records). The study was designed to map the management and follow up of patients in outpatient clinics as reflected from medical records and reporting of patients on diabetes care measures. It was between October 2014 and January 2015.

3.2 Study population

The target population consisted of all type 2 diabetes patients attending the weekly outpatient clinics of the targeted hospitals during the study period. In the specialized diabetes center, only patients' files were included.

Inclusion and exclusion criteria:

Patients included in this study were patients whom diagnosed with type 2 diabetes and started follow up in the target hospitals at least one year prior to the study period. This is to insure inclusion of variables regarding annual diabetes care measures. In addition, included patients should have a follow up card or file filled with variables from previous medical consultations in the target hospitals.

Excluded patients were those with other types of diabetes, critically ill patients and patients who did not attend follow up clinics in the past year.

3.3 Study sample

The study designed as a descriptive study to quantify diabetes care aspects provided by management units measured mainly through review of medical records. Thus, the target population was type 2 diabetes patients attending the outpatient clinics of the health facilities

under study. The sample size of the reviewed medical records was determined using Java applets sample calculator. It was calculated that a sample size of 385 medical records would be required to achieve 95% confidence level. It was estimated through a small pilot study in one of the target hospitals that the number of type 2 diabetes patients attending the outpatient clinic per week was around ten patients. Considering the limited time for data collection, the aim was to interview 250 patients in the three public hospitals.

The eventual sample size was 261 interviewed patients and reviewed medical records in the public hospitals, in addition to 157 reviewed medical records in the specialized diabetes center. In public hospitals, type 2 diabetes is managed within the department of internal medicine, thus, limited number of diabetes patients is available at each outpatient clinic. Consequently, recruitment of participants aimed total coverage of type 2 diabetes patients attending the targeted outpatient clinics during the period of the study.

3.4 Data collection tools

Obviously, the suitable tool for auditing the clinical management in health facilities is observation of the practice of care providers. It was inconvenient to adopt this tool because the recommended diabetes measures are not required at each medical consultation. Certain measures required once per year or every 4 months, e.g. glycosylated hemoglobin test. Moreover, observation in outpatient settings can lead to change in the attitude of care providers.

Eventually, the used data collection tools were:

1. Medical records review checklist: developed from the guidelines on management of diabetes published by the Sudanese federal ministry of health in 2011 and following the recommendations of the World Health Organization (WHO). The guideline showed the required measures for management and follow up of diabetes patients and the period of performing each measure. On the other hand, there were no clear guides on documentation of performed diabetes care measures during the medical consultation. So, the checklist included variables with the assumption that all measures should be recorded. The review checklist was the only tool used in the specialized diabetes center.

2. A structured questionnaire: administered to type 2 diabetes patients attending the targeted outpatient clinic. The questionnaire was used to describe certain demographic and clinical features of patients in addition to recalling of the received diabetes care measures. It was noticeable during the pilot study that requested investigations reports were usually carried by patients, so, additional time during the interview was allocated to check the investigations reports that were brought along with patients but not recorded in follow cards or files.

Variables collected from the medical records review:

A. Diabetes related clinical history:
    1. Symptoms related to diabetes and its complications
    2. History of current diabetes medications
    3. Smoking status
B. Diabetes related physical exam:
    1. Weight measurement and recording of BMI
    2. Recent blood pressure measurement
    3. Feet exam within the last year
    4. Eye exam (fundoscopy) within the last year
    5. Peripheral pulses examination
C. Diabetes related laboratory investigations:
    1. Recent plasma glucose level
    2. Glycosylated hemoglobin level within the last 4 months
    3. Lipids profile for total cholesterol and LDL level
    4. Serum creatinine level (renal function test)
    4. Statistical analysis:

Statistical analyses consisted of descriptive statistics, Chi-square test, t-test and binary logistic regression. The analyses adopted a confidence level of 95% and P-value<0.05 was considered to be statistically significant. The collected data were normally distributed, thus mean value standard deviation was the main presentation. The tested criteria of diabetes care were equally weighted for all patients. Therefore, adherence to each criterion, as documented in medical

records was, presented as percentages (100% is full adherence). The association between two nominal variables was examined using the Pearson's chi-squared test.

Attainment of diabetes care therapeutic targets was quantified using clinical cut-off points as recommended by the standard guideline. Proportion of patients reaching the standard target was presented with percentage of documentation of the tested variable. Logistic regression was used to predict effects of covariates suspected to have association (e.g. health insurance, history of hospitalization, duration and complications of diabetes) on receipt of diabetes care measures. The effect of covariates was presented as odds ratio and confidence interval.

3.5 Data collection procedure

After receiving the ethical approval from the national committee, three public hospitals were chosen as study sites according to availability of type 2 diabetes patients and permission from the hospitals administrations. Pretesting included attending at least one outpatient clinic at each hospital. The aim of pretesting was to understand the organization of outpatient clinics in the targeted hospitals to determine the appropriate method for approaching patients. In addition, the questionnaire was presented to patients to ensure clarity and sequencing of questions. Due to the limited time frame and the weekly and overlapping timing of the outpatient clinics, three research assistants were trained on interview techniques and data extraction. The research assistants were newly graduated doctors and recruited in different times during the data collection period.

Data collection in the specialized diabetes center started at a later time because ethical approval was required locally at the center. The study site was the statistics unit where files of patients attending the outpatient clinics are collected.

During the study, patients were approached either in the waiting room prior to their medical consultation or directly after finishing the meeting with care providers. In the three public hospitals, type 2 diabetes patients were followed up with the internal medicine units. The hospitals had different arrangements for the outpatient clinics. In two hospitals, files were collected by the statistics unit prior to the start of the clinic. The previous arrangements allowed easier identification of patients fulfilling the inclusion criteria as well as faster approach to the patients in the clinic waiting room. In the other hospital, no such arrangement was implemented

so recruitment assistance was offered by care providers. The collaborated care providers identified type 2 diabetes patient and inquired them about the possibility of participation in the study. The patients then were approached by the researcher for further details.

The average time for completing the 12-items questionnaire was 15 minutes, including time for checking the investigations reports carried along with patients. Additional 5 minutes were needed to extract data from the patients follow up cards using the checklist. On average, 20 patients were interviewed weekly.

3.6 Ethical considerations

The study was designed as a quality control study for an ongoing medical practice without introducing new interventions, so participation involved no more than the minimal risk. The study has been ethically approved from the department of health researches in the federal ministry of health as the study is planned to involve more than one state. Additionally, permission to perform the study and extract data from medical records was obtain from hospitals directors.

Verbal consent was obtained from participants after explaining the purpose and plan of the study. Recruited patients were informed that participation is voluntary and refusal will not influence receipt of further care. The reasons for using verbal consenting were:

- More Feasible and less time consuming in the settings of an outpatient clinic.
- More suitable for illiterate and semi-illiterate participants.
- Cultural issues may be raised by patients when signing any kind of document.
- Short time needed for participants and no side effects on patients apart from time needed for the interview.
- Allowing patients to be more interactive.

Communication of the study results:

- The study will be presented as a master's thesis at the institute of health and society, University of Oslo.

- Dissemination of the study results and recommendations to the interested bodies in the Sudanese federal ministry of health and the hospitals directories.
- Transforming the study into an article and publishing in suitable journals.

4. RESULTS

4.1 Response rate

During the study duration, a total of 293 diabetes patients were approached to answer the questionnaire after fulfilling the inclusion criteria. Medical records of the previous patients were reviewed beforehand. Finally, 261 patients agreed to participate in the study, with a response rate of 89, 07%.

4.2 General characteristics

Two hundred and sixty one patients aged twenty two years to ninety years were interviewed in outpatient clinics of three major public hospitals in Khartoum and Gezira states. Information on diabetes management was reviewed from their follow up cards. Table 4.2.1 includes details of the demographic and clinical backgrounds of patients.

The average age of the study sample was in the mid-fifties (54 ±14.5) and 50.2% of all patients were in the age group 45-64 years. More females were represented in the study (54.8% female vs. 44.2% male), although the difference was not statistically significant (Stata Two-sample test of proportions (z=1.54, P=0.122)). Majority of patients (59.8%) were using oral antidiabetic agents for glycemic control compared to minor percentage (3.8%) were controlled by diet alone. Almost 40% of the study sample lacked health insurance coverage. A third of the patients reported to have high blood pressure either before or after diagnosis with Type 2 Diabetes. Although, 18.0% (n=47) were current smokers including twelve females, enquiry or advice on smoking cessation was lacking with only 13% of patients having a documentation on smoking status or advice on smoking cessation.

In the specialized Diabetes center (Table 4.2.2), one hundred sixty two patient's files were reviewed. Mean age was fifty six years and ranged from 29-90 years. Mean duration since diagnosis with type 2 diabetes was ten years (10.0 ±7.0). Almost sixty percent of the study sample were females (n=94). Although, weight was routinely measured in each visit (unless is disabled), measurement of height, and thus BMI, was only available in 63% of the studied patients. The mean BMI of the documented recordings was twenty six. Oral antidiabetic medications were documented in 68.9% of patients (n=104), while eleven patients (7.3%) used no Diabetes medications.

Table 4.2.1: Demographic and clinical data for the 262 interviewed diabetic patients in Public hospitals:

Characteristics	No. (%)	Mean ± SD
Age, years		54 ±14.5
Duration since diagnosis with Diabetes, years		8.1 ±7.6 (range 1—38)
Gender		
Female	143(54.8%)	
Male	118(45.2%)	
DM medications		
None (Diet and exercise only)	10(3.8%)	
Oral antidiabetic agents	156(59.8%)	
Insulin injections	48(18.4%)	
Combination of oral agents and Insulin	47(18.0%)	
Patients with private Glucometer	56(21.5%)	
Patients enrolled in the Health insurance scheme	154(59.0%)	
Smoking status		
Nonsmokers	198(75.9%)	
Active smokers	47(18.0%)	
Previous smokers	16(6.1%)	
Comorbidities/ Organs affected by T2DM		
Hypertension	86(33.0%)	
Foot (peripheral neuropathy)	65(24.9%)	
Eye	68(25.9%)	
Heart (Coronary artery disease)	30(11.5%)	
Kidney (Nephropathy)	14(5.4%)	

Table 4.2.2: Demographic and clinical features reviewed from patients files in the Specialized Diabetes center:

Characteristics n=157	No. (%)	Mean ± SD (Range)	Documentation (%)
Age, years		56 ±11.4 (29-90)	**100%**
Duration since diagnosis with Diabetes, years		10.0 ±7.0 (2-40)	**100%**
Gender			**100%**
Female	94(59.9%)		
Male	63(40.1%)		
Body Mass Index (BMI)		26 (17-43)	**63%**
DM medications			**96%**
None (Diet and exercise only)	11(7.3%)		
Oral antidiabetic agents	104(68.9%)		
Insulin injections	12(7.9%)		
Combination of oral agents and Insulin	24(15.3%)		
Smoking status			**86%**
Nonsmokers	131(83.5%)		
Smokers	26(16.5%)		

4.3 Documentation of diabetes medical consultation

In the public hospitals, all the tested Diabetes follow up exams and investigations, except for those considered as routine such as BP checks and blood Glucose measurements, were below 30% documented. Frequency of documentation was ranging from 9.2% who performed eye exam (Fundoscopy) to 22.9% who had their glycosylated hemoglobin checked. Highly documented areas included Diabetes history, complications history and measurement of BP. Smoking history was documented in 13% of patients only.

One hundred and seventy six patients (67.2%) had at least one blood glucose level test (FBG/RBG) during the past year but only 22.9% patients documented a glycosylated hemoglobin measurement. However, there were no significant demographic differences between them and patients who did not have glycosylated hemoglobin documented.

Percentages of documentation in the specialized Diabetes center showed higher values in all tested variables. Statistical testing of proportions revealed significant differences in all similar variables except for documentation of glycosylated hemoglobin measurement, which was 22.9% in the public hospitals compared to 35% in the specialized Diabetes center. Eye exam (Fundoscopy) was the least documented variable in both public hospitals (9.2%) and the specialized Diabetes center (22.9%).

Table 4.3.1 Comparison between frequency of documentation of Diabetes care aspects in public hosptals and the specialized Diabetes center:

	Public hospitals: N = 262	**The Specialized Diabetes Center: N = 157**	**P-value**
Item	n (%)	n (%)	
1. **Long term and/or DM history**	197(75.2)	157(100.0)	<0.01
2. **Complications history**	190(72.0)	157(100.0)	<0.01
3. **Drugs History / current drugs**	229(87.4)	151(96.2)	<0.01
4. **Smoking status**	36(13.0)	135(86.0)	<0.01
5. **Serial PB readings**	185(70.6)	145(92.4)	<0.01
6. **BMI/Weight measurement**	47(17.9)	100(63.7)	<0.01
7. **Blood Glucose level (RBG/FBG)**	176(67.2)	155(98.7)	<0.01
8. **HBA1c (within 4 months)**	60(22.9)	55(35.0)	0.155
9. **Foot examination**	37(14.1)	72(45.9)	<0.05
10. **Peripheral Pulses Examination**	59(22.5)	102(65.0)	<0.01
11. **Retinal screening (Fundoscopy)/ Referral to ophthalmologist**	29(9.2)	36(22.9)	<0.01
12. **Lipids Profile**	45(17.2)	61(38.9)	0.018
13. **Urine Protein/Albumin**	41(15.6)	60(38.2)	0.012
14. **Renal Function Test**	77(29.4)	72(45.9)	0.030

Patients were asked, in the questionnaire, about receipt of selected Diabetes care measures, namely, eye exam (fundoscopy), foot exam by health care professional, PB measurement and weight measurement. Moreover, the investigator checked the results of certain investigations carried with patients, such as glycosylated hemoglobin, renal function test and lipids profile. The produced results include both the reported measures by patients and the ones detected by the investigator.

In table 4.2.2, diabetes care measures reported by patients in the questionnaire are compared to their frequency of documentation in the patients follow up cards. In general, patients received more Diabetes care measures than it is documented. These differences were statistically significant in reporting of fundoscopy, PB checking and renal function tests. The highest difference was noted in reporting of fundoscopy as it is documented in 9.2% of follow up cards while 29.5% of patients reported having fundoscopy done in the past year.

Reporting of received Diabetes care measures by patients (Questionnaire) ranged from 87% as in BP checking to 22.2% who received foot exam in the past year.

Table 4.3.2: Comparison of selected Diabetes care measures obtained from the medical records and the patients questionnaire:

Measurement	**Questionnaire No.(%) n=261**	**Checklist No.(%) n=261**	**P-value**
Fundoscopy/referral to ophthalmologist	77(29.5)	29(9.2)	<0.01
Foot exam by HC personnel	58(22.2)	37(14.1)	0.32
PB measurement by Physician	227(87.0)	185(70.6)	<0.01
Weight measurement	80(30.7)	47(17.9)	0.10
HBA1c within the last 4 months	93(35.6)	60(22.9)	0.08
Renal function test within the last year	129(49.4)	77(29.4)	<0.01
Lipids profile within the last year	82(31.4)	45(17.2)	0.08

4.4 Achievement of diabetes therapeutic targets in the specialized center

This section includes results obtained only from the specialized diabetes center. The collected data from the public hospitals were extremely deficient regarding the values of diabetes care measures and investigations.

Glycemic control:

In the sample of 157 patients' files, 35% of patients had their HBA1c recorded. Out of these patients only twelve patients (21.8%) reached the therapeutic target of less than 7% recommended by the standard guidelines.

Blood Pressure control:

Systolic and Diastolic Blood Pressure (BP) measurements were noted in 93.6% of patient files, revealing mean values of 125 mmHg and 77 mmHg, respectively. Considering the target value for adequate control of Blood Pressure of less than 130/80, one hundred and fourteen patients (76.6%) met the standard target.

Diet and BMI:

Within the study sample managed in the specialized Diabetes center, seventy patient files (26.8%) documented receipt of dietary consultation in the past year. Body Mass Index (BMI) was recorded in 30% (n=100) of patient files and the mean value was 26 kg/m2. Out of these patients, forty four patients (44%) were recorded to have BMI less than 25 kg/m2.

Lipid control:

39.5% of patient files contained values for total cholesterol and Low Density Lipoprotein (LDL) tests. The management target success rate was 74% for total cholesterol (the target is less than 200 mg/dl) but only 37% of patients reached the target LDL level of less than 100 mg/dl.

Table 4.3 Documentation of diabetes and Diabetes complications risk factors indicators of 157 reviewed clinical records in the specialized Diabetes center:

Clinical Test/Measure	Percentage of Documentation, n=157	Mean value ± SD	Standard target	N(%) of patients achieving the targets
Systolic BP, mmHg	93.6%	125.3 ±17.4	< 130	114(76.6)
Diastolic BP, mmHg	93.6%	77.6 ±10.6	< 80	115(78.2)
BMI, Kg/m	63%	26 ±4.5	18.5-24.9	44(44.0)
HBA1c,%	35.0%	8.1 ±2.0	<6.5	12(21.8)
Total cholesterol, mg/dl	39.5%	176.4 ±41.4	<200	46(74.2)
LDL, mg/dl	39.5%	113.0 ±41.9	<100	23(37.1)
Serum Creatinine	45.9%	1.09 ±0.72	<1.00	42(58.3)

BP: blood pressure, HBA1c: glycated hemoglobin, RBG: random blood glucose level, FBG: fasting blood glucose level, LDL: low density lipoprotein

4.5 Factors affecting performing annual diabetes care measures:

In table 4.4, selected independent variables were included in binary logistic regression model to predict their influence on receipt of investigations of glycemic control and screening of complications. The suggested covariates include health insurance, past history of hospitalization and duration since diagnosis with Diabetes. The odds of receiving the selected services were approximately equivalent for patients with health insurance and no health insurance. Patients

with longer duration since diagnosis with Diabetes showed greater odds of receiving eye exam (fundoscopy). The proportions of patients receiving glycosylated hemoglobin and renal function tests were significantly higher among patients with positive past history of hospitalization.

Table 4.4 Binary logistic regression analysis predicting receipt of Diabetes follow up investigations according to significant covariates:

INVESTIGA-TION	Fundoscopy n=77		HbA1c n=93		RFT n=129		Lipid profile n=82	
COVARIATE	OR (95% CI)	P-value	OR (95% CI)	P-value	OR (95% CI)	P-value	OR (95% CI)	P-value
Insurance	1.5 (0.8-2.8)	0.1	1.4 (0.8-2.4)	0.2	1.1 (0.6-1.9)	0.6	1.0 (0.6-1.7)	0.8
Hospitalization	0.5 (0.3-0.9)	**0.04**	0.8 (0.5-1.4)	0.5	2.6 (1.6-2.4)	**0.000**	1.3 (0.7-2.2)	0.2
Duration of DM	1.06 (1.0-1.1)	**0.001**	1.01 (0.9-1.05)	0.3	1.0 (0.9-1.0)	0.2	1.0 (0.9-1.0)	0.5

HBA1c: glycated hemoglobin, RFT: renal function test, OR: odds ratio, n: number of patients who receipt the investigation, **Bold** if $P < 0.05$

4.6 Purpose of annual Diabetes care measures

Annual Diabetes care measures, such as renal function test, retinal screening (fundoscopy), foot assessment and lipids profile, are recommended screening tools to detect long term Diabetes complications. The following tables compare the proportions of relevant tests among patient groups with or without end organs damage.

Table 4.5.1 Association between Diabetes complications and relevant screening tests or exams:

	RFT DONE	**RFT NOT Done**	**P-value**
Kidney problems	12 (85.7%)	2 (14.3%)	**0.005**
No kidney problems	117 (47.4%)	130 (52.6%)	
	Fundoscopy DONE	**Fundoscopy NOT Done**	
Eye Problems	38 (55.9%)	30 (44.1%)	**0.000**
No eye problems	39 (20.2%)	154 (79.8%)	
	Foot exam DONE	**Foot exam NOT Done**	
Foot problems	22 (37.9%)	36 (62.1%)	**0.009**
No foot problems	43 (21.1%)	160 (78.8%)	
	Lipids profile DONE	**Lipids profile NOT Done**	
Heart problems	8 (9.7%)	74 (90.2%)	0.55
NO heart problems	22 (11.1%)	175 (88.8%)	

Table 4.5.2 Binary univariate logistic regression predicting the effects of developing Diabetes complications on performing complications performing measures:

Complication vs. Test or exam	**OR (95% CI)**	**P-value**
Eye problems vs. Fundoscopy	5.2 (2.7-9.0)	**0.000**
Foot problems vs. Foot exam	2.2 (1.2-4.2)	**0.010**
Kidney problems vs. RFT	6.7 (1.4-30.4)	**0.014**
Heart problems vs. Lipids profile	1.3 (0.5-3.0)	0.551

5. DISCUSSION

5.1 Overview

The results of our study is discussed in the context of the national guidelines on management of type 2 diabetes in Sudan, in addition to similar regional and international studies in case management and barriers to diabetes care.

In the current study, females were found to have a higher ration than males. This trend is compatible with several international and regional reports indicating higher prevalence of type 2 diabetes among females (37-40). As our study was hospital based, it is expected that females will have greater attendance and better care seeking behavior. For example, Feaz B. et al(41) studied the role of gender in attending type 2 diabetes clinics and they showed that 74.2% of attendants were females.

In general, the results indicated that the diabetes care in outpatient clinic was inadequate. The adherence to the management guidelines differs between areas of diabetes care. High adherence area was clinical history. Care providers showed greater compliance with documenting the clinical history of diabetes, related complications and medications as the percentages were 75%, 72% and 87% respectively. Smoking history was an exception as it was documented in only 13% of reviewed medical records. As noted from the patients' questionnaire, it was disturbing that 47 patients (18%) were current smokers given the close relation between smoking and diabetes related complications. Another interesting observation was that all the patients who were asked about smoking status were males. It may be due to cultural reasons that asking females about smoking status is not appropriate.

An important factor in assessing the management of type 2 diabetes is measuring the number of patients achieving the standard targets of glycemic control, metabolic control and complications screening. The available data in the public hospitals on the results of different diabetes investigations was lacking. Thus, achievement of diabetes therapeutic targets was studied in the specialized diabetes center only. Nevertheless, certain results of our study such as hospitalization, complications and associated comorbidities can reflect on the management

outcome. The results from patients' questionnaire showed that more than 25% of patients had at least one diabetes related complication. One third of patients were diagnosed with hypertension which can be a diabetes related complication or a coexisting disease. Furthermore, 36.4% of patients reported previous hospitalization due to diabetes related causes, although rate of hospitalization is usually higher among diabetes patients than in the general population.

Another important factor in the follow up of diabetes patients is medical documentation. As suggested by the results, patients reported excess of received diabetes measures in comparison to what is documented. The previous finding indicates a deficiency in documentation of the measures performed during the medical consultations. Documentation of diabetes visits was more competent in the specialized center, which could be due to the using of predesigned medical files and training of staff on management of diabetes.

Somewhat surprisingly, 66.3% of patients reported monthly visits for follow up of diabetes given that outpatient visits are recommended every three months. The previous finding was higher than other published studies including ones conducted in developed countries (42-45). We cannot explain why patients attended diabetes clinics more frequently other than speculate on certain factors. First, almost 60% of our patients were enrolled in health insurance coverage. In order to purchase medications funded by the health insurance, the request must be performed by a physician during the outpatient clinic. Second, only 21% of patients had home glucometer, thus monitoring of glycemic control was based on laboratory testing. Third, underutilization of HbA1c in glycemic monitoring, which was documented in 22.9% of patients may represent another factor. In contrast to HbA1c, which is required 2-3 times a year, blood glucose tests (FBG and RBG) are required more frequently. Lastly, the limited time during outpatient clinics and the delay in obtaining laboratory results force patients to repeat follow up visits.

5.2 Glycemic control

Among our patients, 67% had blood glucose level tests (FBG or RBG) documented in their medical records. The blood glucose tests are beneficial in measuring the current blood glucose level but not suitable in monitoring long term glycemic control. Several guidelines agreed on HbA1c as the gold standard test for monitoring glycemic control (25-27), although there is

variation on the recommended target level. The test is currently recommended for diagnosing new cases of diabetes (44). Moreover, several studies indicate that glycosylated hemoglobin is a prognostic factor in developing certain diabetes complications (49-51). Reduction of HbA1c by 1% reduces the risk of microvascular complications (retinopathy, nephropathy and neuropathy) by 40% (52) and reduces mortality by 21% (53).

It was surprising that only 22.9% of medical records documented HbA1c level within the past 4 months. The percentage was higher when patients were interviewed (35% of patients had HbA1c reports). Although there is discrepancy between performance and documentation, both remain below the expected level. In comparison to the specialized diabetes center, the percentage showed no statistical difference as 35% of records contained values for HbA1c. These percentages are comparable to similar studies performed in Lebanon, Cyprus and Nigeria (40, 46, 47), in contrast to the higher performance rate shown in several studies in developed countries (41-44).

The previous results can reflect shortage on performance or documentation of HbA1c by care providers. Also, it is usually cited that one of the barriers to the use of HBA1c is the high cost of the test, which can reach, in Sudan, 10 times the cost of RBG. Currently, The WHO has called to increase the availability of the test in lower and middle income countries (LMICs) by reducing the cost. Therefore, the test is not yet an established practice in LMICs as compared to high income countries.

5.3 Lipids control

Dyslipidemia is a major cause of cardiovascular disease in type 2 diabetes patients. It is recommended that screening for lipids abnormalities should be conducted annually. Lipids lowering drugs are recommended in patients with levels of cholesterol and LDL higher than 200 and 100 mg, respectively. In our study, 17% of medical records included results of lipids profile test while 31% of patients had reports of lipids profile. Although, the documentation underestimated the performed number of tests, both percentages shows low adherence to the recommendations. The figures from the specialized diabetes center were significantly higher as 38.9% of patients' files contained values of lipids profile test.

Another observation was that all medial files documented measures of total cholesterol and LDL while other items of the lipids profile such as HDL and triglycerides were not included. The previous observation may be due to shortage in the performance of care providers or the nature of the available lipids profile test in Sudan. It is frequently cited that hypertriglyceridemia is the most commonly detected lipids abnormality in type 2 diabetes patients (30-32). Moreover, a study conducted in Sudan to describe the patterns of lipids changes in 250 type 2 diabetes patients compared to a control group of healthy people (33). Levels of HDL and triglycerides were the only items that showed significant difference between the two groups. In the previous study, almost half of patients showed an abnormality in lipids profile.

5.4 Barriers to care

There are several barriers to achieve comprehensive diabetes care, which can be related to patients, care providers or the health system. The cross sectional design of our study is not suitable for detecting causation of the shortage in the management practice. In the analysis, we tried to assess the association between receiving diabetes care measures and certain factors, namely health insurance, previous hospitalization and duration of diabetes. Health insurance coverage is commonly indicated as a factor in access to diabetes care (34-36). Although the odds of receiving diabetes care measures and investigations were higher among patients with health insurance, the difference was not statistically significant. History of previous hospitalization usually increases the chances of receiving comprehensive care because of the increase in patients' contact with the health system. Unlike the limited time given to patients in an outpatient clinic, during hospital stay physicians use more extensive care plans. In our sample, the odds of receiving certain measures such as renal function test and dilated eye exam (fundoscopy) were significantly higher in patients with previous history of hospitalization. Receiving of fundoscopy was also significantly associated with the duration of diabetes. Patients with longer duration since diagnosis with diabetes had higher chances of receiving fundoscopy.

Annual screening for diabetes patients is recommended to prevent the diabetes related complications by detecting the high risk patients and introducing the relevant clinical interventions. Renal function test, foot exam and fundoscopy are directly related to the screening

of diabetes associated kidney, foot and eye complications, respectively. An important finding of the study was that the previous tests are more frequently used in patients with established complications. To elaborate more, 85% of patients with kidney problems received renal function test in the past year compared to 47% of patients without kidney problems. Moreover, fundoscopy was performed in 56% of patients with eye problems compared to 20% of patients without eye problems. Lastly, 38% of patients with diabetes related foot problems received foot exam compared to 21% of the patients without the foot problems. The previous finding was highly statistically significant ($p<0.001$). Although our study design and methods are not confirmatory, the previous findings could indicate that some physicians tend to use these tests for diagnosis and follow up purposes rather the recommended annual screening.

5.5 Comparison of process of care measures

Audit of the management practice of diabetes is frequently based solely on clinical records. Several studies assess the management according to the frequency of documentation of diabetes care measures. Table 5.5 compares the percentages of documentation between our study and other relatively similar studies. Some of these studies often have different objectives. Consequently, some of the diabetes care measures are missing in the table 5.5.

Table 5.5: Comparison of documentation of diabetes care process measures:

Country/YOP	Sample size	Percentage of recorded received diabetes care measure					
		BMI	BP	Foot exam	HbA1c	fundoscopy	Lipids profile
Current study 2015	262	17.9	70.6	14.1	22.9	9.2	17.2
Saudi Arabia[54] 2005	138	39	100	27	73	51	69
Lebanon[47] 1999	204		85.8	31.4	39.7	50	93.1
Turkey[45] 2012	1790	57.5	84.8	64.6		42.6	89.7
Bosnia[42] 2008	536	25.0	67.2	53.4	26.5	53.7	72.9
England[55] 2001	19174		83.6	70.4	83.0	64.6	71.4

5.6 Validity and Limitations of the study

The cross sectional design of the study restricts the possibility of examining the causation of low adherence to the management guidelines. Moreover, review of medical records might not be highly indicative of the performance of care providers. In outpatient settings, care providers has the ability to perform appropriate medical documentation compared to emergency settings. Nevertheless, we believe that certain areas such as counseling and physical exams will be less documented. Selection bias is expected as sampling targeted high capacity hospitals only. The reason was to achieve the desired sample size given the limited data collection period and the paucity of type 2 diabetes patients in small health facilities.

In addition, two hospitals authorities refused to participate in the study, which may alter the obtained results. Patients were asked to report on diabetes care measures received in the past year, representing a possibility of recall bias. Finally, research assistants were recruited in data collection because outpatient clinics were often conducted in the same time in different hospitals. Although, the research assistants were trained on reviewing of medical records and interviewing of patients, minor differences may occur in the collected data.

The previous limitations may reduce the internal and external validity of the study, but it is valuable in describing the management practice for type 2 diabetes in Sudan.

6. Conclusions and recommendations

6.1 Conclusion

The aim of the study was to describe the management and follow up of type 2 diabetes patients in relation to the national guidelines. The study identifies various areas of suboptimal diabetes care for potential improvement. Based on revised clinical notes, screening for diabetes complications is a low adherence area as the screening tests were documented in less than one third of the tested sample.

The study underscored the discrepancy between the documented diabetes care measures and the performed measures as reported by patients, highlighting a deficiency in proper documentation of medical consultations.

It was alarming to note that the comprehensive case management is inadequate in most areas of diabetes care. Thus, it emphasizes the importance of multidisciplinary approach to implement the guidelines of diabetes management as well as screening and prevention of its complications. It's possible to assume that the study confirms the presence of a gap between the practical guidelines and the actual practice in relation to the national guidelines in Sudan.

6.2 Recommendations

The study confirms the gap between the practical guidelines and the actual practice relation to the national guidelines in Sudan. As various shortcomings in diabetes care were identified, we would like to suggest the following recommendations:

1) To develop training programs for diabetes management that focus on the preventive aspect and screening of complications rather than glycemic control and symptomatic treatment only.

2) Diabetes is a complex disorder. There is an urgent need for a systematic approach to care which should be facilitated by the use of Disease register Recall system, Flow charts and Review charts.

3) To initiate a nationwide standard chronic care model that follows strictly guidelines as it has the potential to improve care and reduce costs.

4) To develop a standardize assessment tool for routine auditing of diabetes care and follow up.

5) To conduct studies with larger sample size and prospective design to assess the barriers to diabetes care and quantify the outcome of diabetes management.

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Annexes

Annex 1 Medical records review tool

University of Oslo

International Community Health

Diabetes Management Guidelines in Outpatient clinics
Records review Checklist

No.	Review topics	Response category*
	Section 1: Elements reviewed REGULARLY	
	Long term and/or recent diabetes history	
	Complications history and/or symptoms	
	Drug history / current drugs	
	Smoking status	
	Blood Pressure measurement (serial readings)***	
	Weight / Height ***	
	Serial blood glucose tests ***	
	HbA1c tested within 4 months ***	
	Section 2: Elements reviewed ANNUALLY**	
	Foot examination	
	Peripheral Pulses examination	
	Eye vision examination(Retinal screening)	
	Lipid profile (Esp. Cholesterol/ LDL ***)	
	Urine protein / Urine albumin excretion***	
	Serum creatinine***	

Hospital type: ..... Date of case extraction: ..../..../.....

Patient age: .....

Annex 2 Patients' questionnaire

University of Oslo

International Community Health

Diabetes Management Guidelines in Outpatient clinics
Questionnaire for type 2 diabetes patients

Date__/__/__

Q1 Age: _____

Q2 Gender: ☐ Female ☐ Male

Q3 Duration since diagnosis of Diabetes: _____

Q4 Do you have Glucometer (Blood sugar measuring device) at home?

☐ Yes ☐ No

Q4.1 How often do you check your blood sugar at home? _____

Q4.2 Do you record your blood sugar test results for your doctor visits?

☐ Yes ☐ No

Q5 Do you have a meal plan for Diabetes?

☐ Yes ☐ No

Q5.1 How often do you follow this plan?

☐ Never ☐ Seldom ☐ Sometimes ☐ Usually ☐ Always

Q6 Do you use tobacco (smoke cigarettes)?

☐ Yes How many_____ ☐ ☐ No Quit, how long ago? _____

Q7 In the last 12 months, how many times have you had a diabetes routine checkup (excluding the current visit)?

☐ None ☐ Once ☐ Twice ☐ Three or more
Don't know

Q8 Check any of the following tests/ procedures the patient had in the last 12 months:

☐ Dilated eye exam (Fundoscopy)

☐ Foot exam - self

☐ Foot exam - Healthcare professional

☐ Dietary consultation - Dietician

☐ Blood pressure measurement - Healthcare professional
_____

☐ Weight measurement - Healthcare professional
_____

☐ HbA1c (a test to measure the average control in the last 3 months) _____ (last available result)

☐ Serum creatinine/ RFT
_____ (last available result)

☐ Cholestrol level/ Lipid profile
_____ (last available result)

Q9 Do you have any of the following?

☐ Eye problems

☐ Kidney problems

☐ Numbness/tingling/ loss of sensation in your feet

☐ High blood pressure

☐ Heart problem

Please list any other medical conditions

_____

_____

____

Q10 In the last 12 months, how many times you have been admitted to the hospital (overnight stay)?

_____

Q10.1 What was the reason for your most recent hospital stay related to?

☐ DM ☐ something else ☐ don't know

☐

Q 11 Do you take Diabetes medications?

☐ Yes ☐ No

Q11.1 Choose the medications that apply to the patient:

☐ Oral antidiabetic only

☐ Insulin injections only

☐ Combinations of oral antidiabetics and insulin injections

Q11.2 Do you take any other medications?

☐ Yes ☐ No

Q12 Do you have a valid health insurance?

☐ Yes ☐ No

Annex 3 NORWAY (REK) ETHICAL CLEARANCE CERTIFICATE

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Officer:	Phone:	Our date:	Reference
REK south-east	Gjøril Bergva	22845529	25.06.2014	2014/843/REK sør-øst D
			Your date: 13.05.2014	

Gunnar Aksel Bjune
postboks 1130 Blindern
0317 Oslo

2014/843 Vurdering av Type 2 Diabetes Mellitus forvaltningspraksis i sudanske offentlige sykehus

In regards to your application considered by the Committee on the 11th of June 2014.

Responsible for research: University of Oslo
Chief investigator: Gunnar Aksel Bjune

Project summary
Type 2 diabetes is a growing problem in Sudan. WHO has issued guidelines for its mangament and these have been adapted by Sudanese Health authorities. However, the implementation is slow. The objective of this study is to describe the management practice of type2 DM in Sudan healthcare facilities and to what extent the guidelines are known and have been implemented. Data from medical records will be analyzed against a preformed checklist, and care providers will be interviewed. The results of the study will help the policy makers in Sudan to evaluate the quality of management practice of Type 2 Diabetes and the extent of implementation of the national guidelines.

We hereby confirm that the Regional Committee for Medical and Health Research Ethics, section South-East D, Norway has received the project "Assessment of Type 2 Diabetes Mellitus management practice in Sudanese public hospitals" for review. The project was discussed on the 11th of June 2014.

The Regional Committee has the authority to either approve or disapprove medical and health research studies conducted within Norway, or by Norwegian institutions, in accordance with ACT 2008-06-20 no. 44: Act on medical and health research (the Health Research Act "HRA").

Pursuant to section 4 of the HRA, the following definition applies for medical and health research: *Activity conducted using scientific methods to generate new knowledge about health and disease*. The purpose of this project is to describe the management practice of type2 DM in Sudan healthcare facilities and to what extent the relevant guidelines are known and have been implemented. The Regional Committee considers that the study will bring new knowledge about the health-care system rather than new knowledge about health and disease.

Hence, the above mentioned study falls outside the scope of the HRA, and the project is exempt from review in Norway, cf. §§ 2 and 4 of The Act. Even though the project can be implemented without the approval the Regional Committee for Medical Research Ethics, it may be subject to local legal requirements (i.e. any necessary permits must be collected from the authorities in Sudan). To the extent that identifiable personal data will be processed, the Personal Data Act will apply.

Besøksadresse:
Gullhaugveien 1-3, 0484 Oslo

Telefon: 22845511
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no/

All post og e-post som inngår i saksbehandlingen, bes adressert til REK sør-øst og ikke til enkelte personer

Kindly address all mail and e-mails to the Regional Ethics Committee, REK sør-øst, not to individual staff

Please do not hesitate to contact the Regional Committee for Medical and Health Research Ethics, section South-East D (REK Sør-Øst D) if further information is required.

Decision
The study is exempt from review, cf. §§ 2 and 4 of The Act.

The decision of the Committee may be appealed to the National Committee for Research Ethics in Norway. The appeal will need to be sent to the Regional Committee for Research Ethics in Norway, South-East D. The deadline for appeals is three weeks from the date on which you receive this letter.

Yours sincerely

Finn Wisløff
Professor em. dr. med.
Leder

Gjøril Bergva
Advisor

Copy:
Universitetet i Oslo ved øverste administrative ledelse: universitetsdirektor@uio.no
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Annex 4 SUDAN ETHICALCLEARANCE CERTIFICATE

Republic of Sudan
Federal Ministry of Health

HEALTH RESEARCH COUNCIL

NATIONAL RESEARCH ETHICS REVIEW COMMITTEE

Date 19/11/2014

Ethical Clearance Certificate

*This is to certify that the proposal entitled (**Assessment of Type 2 Diabetes management practice in Sudanese public hospitals: Review of follow up outpatient cards and interview patient questionnaire during the period of October- January 2015**) submitted by **DR. Mazin Yousif Elsharif Elhendi** from **University of OSLO** has been approved by **the National Health Research Ethics Committee, Federal Ministry of Health** to be conducted in the Sudan.*

NB

The principal investigator is requested to submit the final report to the Research Directorate- Federal Ministry of Health.

Federal Ministry of Health

19/11/2014
Dr. Iman Abdalla Mustafa
Reporter of the
National Research Ethics Review Committee